

**Amendment**

**U.S. Patent Application No. 10/759,218**

**REMARKS**

Claims 47-72 are pending in the subject application. Claims 47-68 have been examined and stand rejected. Claims 47 and 59 have been amended, and new claims 69-72 have been added, and support for such claim amendments and addition of new claims is provided throughout the specification. Favorable reconsideration of the application and allowance of all of the pending claims are respectfully requested in view of the following remarks.

In response to the Examiner's comments regarding the listing of references being in an Information Disclosure Statement, Applicants note that an Information Disclosure Statement, including a PTO-1449 form, was filed on November 1, 2004 (shortly before the mailing date of the present Office Action). This Information Disclosure Statement includes all of the references cited in the application. Applicants request that the Examiner initial the references cited in the PTO-1449 form and return the initialed copy of the PTO-1449 form to Applicant along with the next official communication from the Office.

Claims 47-58 are objected to for an informality in claim 47, where the Examiner requires a change of the language of "within said base" in claim 47 to --within said receptacle--. Claim 47 was amended in accordance with the Examiner's requirements, and Applicants request that this objection be withdrawn.

Claims 47-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various claims of U.S. Patent No. 6,722,782. A terminal disclaimer accompanies this Amendment, along with the corresponding fee, to overcome these obviousness-type double patenting rejections and shows that the conflicting patent is commonly owned with this application. Accordingly, the Examiner is requested to withdraw these rejections of the claims.

Claims 47-49, 51, 52, 54, 59-61, 63, 64 and 66 stand rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 5,875,282 to Jordan et al. ("Jordan"). In addition, claims 47-49, 51-53, 59-61 and 63-65 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,989,238 to Ginsburg in view of Jordan; claims 47-49, 52, 54, 55, 58-61, 64, 66 and 67 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No.

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4,336,435 to Kashyap et al. (“Kashyap”) in view of Jordan; claim 56 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Jordan in view of U.S. Patent No. 4,532,414 to Shah et al. (“Shah”); and claims 57 and 68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jordan in view of U.S. Patent No. 4,585,441 to Archibald. Applicant appreciates and acknowledges the Examiner’s indication that claims 50 and 62 contain allowable subject matter. Applicant respectfully traverses the above-noted rejections based upon the above amendments to the claims and in view of the remarks as set forth below.

Initially, it is noted that the claimed invention is directed to a medical device that directly measures the temperature of a medical item placed within the device and provides an indication of the temperature of the medical item via a display. Further, while the medical device can be implemented for use with any number of different thermal treatment systems (e.g., warming units and/or other heating and/or cooling systems), the medical device by itself does not include any heating element or other heating device and is further not designed to directly (i.e., by itself) heat or cool the medical item placed within the medical device. This is in direct contrast to the medical heating devices described in the art cited and relied upon by the Examiner to reject the claims.

Independent claim 47 was amended to recite medical device for visually indicating a temperature of a medical item placed therein comprising: a base and at least first and second panels attached to said base; a receptacle defined between said first and second panels for receiving said medical item within said receptacle, wherein said medical item has a particular temperature range for utilization; and a temperature sensor assembly to directly measure medical item temperature and visually indicate said measured medical item temperature. Amended claim 47 further recites that said medical device is configured such that any thermal treatment of said medical item received within said receptacle occurs only via heat transfer between said medical item and an external environment surrounding said medical device.

Similarly, independent claim 59 was amended to recite a method of visually indicating a temperature of a medical item placed in a medical device, wherein said medical device includes a base and at least first and second panels attached to said base and a receptacle defined between

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said first and second panels, said method comprising the steps of: (a) receiving said medical item within said receptacle defined between said first and second panels of said device, wherein said medical item has a particular temperature range for utilization; and (b) directly measuring medical item temperature and providing a visual indication of said measured medical item temperature via a temperature sensor assembly. Amended claim 59 further recites that said medical device is configured such that any thermal treatment of said medical item received within said receptacle occurs only via heat transfer between said medical item and an external environment surrounding said medical device. None of the references relied upon by the Examiner discloses or suggests the combined features of amended claims 47 and 59.

Jordan describes a medical device 10 for warming patient fluids that includes heating elements 92 to heat a heat exchanger bag 16 inserted within the device housing (see Col. 6, line 20 to Col. 8, line 21 and Figures 1-4 of Jordan). The medical device described in Jordan further includes a sensor to measure the temperature near a fluid path outlet 28 of the heat exchanger bag 16 and also a thermal feedback control system to control heating of the heat exchanger bag based upon temperatures measured by the sensor.

Jordan fails to disclose or suggest a medical device or a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device is configured such that thermal treatment of a medical item received within a receptacle of the medical device occurs only via heat transfer between the medical item and an external environment surrounding the medical device as recited in claims 47 and 59. In contrast, Jordan requires the use of a heater and a control system that utilizes the measured temperature within the device to control heating within the device. Since Jordan fails to disclose every recited feature of each of claims 47 and 59, these claims are not anticipated by Jordan and the Examiner is requested to withdraw the rejection of these claims based solely upon this reference.

In addition, dependent claims 48, 49, 51, 52, 54, 56-58, 60, 61, 63, 64 and 66 depend from one of claims 47 and 59 and thus include all of the limitations of their parent claims. Accordingly, these dependent claims are not anticipated by Jordan, or rendered obvious in view

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of Jordan with Shah or Archibald, and the Examiner is requested to withdraw the rejections to these claims based upon these references.

Regarding the rejection of claims 47 and 59 as being obvious over Ginsburg in view of Jordan, Ginsburg describes an infusion system for introducing fluids into the body within desired temperature ranges. The system 10 of Ginsburg includes a chamber 28 to receive a fluid reservoir 30, a thermistor 34 within the chamber 28 to monitor the temperature of the reservoir 30, and a temperature altering element 32 to heat the walls 26 of the chamber (see Col. 4, line 35 to Col. 6, line 4 and Figures 1 and 2 of Ginsburg). Ginsburg further describes different mechanisms for pressurizing the reservoir 30 and a processor to control the pressurization and flow of fluid from the reservoir once the fluid has reached a desired temperature, as indicated by the thermistor 34. Clearly, Ginsburg requires heating of the reservoir or medical item received within the system to ensure that fluid is at a desired temperature prior to delivery to a body.

Therefore, Ginsburg fails to disclose or suggest a medical device or a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device is configured such that thermal treatment of a medical item received within a receptacle of the medical device occurs only via heat transfer between the medical item and an external environment surrounding the medical device as recited in claims 47 and 59. In addition, as noted above, Jordan also fails to disclose or suggest the combined features of each of claims 47 and 59. Since no combination of Ginsburg with Jordan describes or suggests every recited feature of each of claims 47 and 59, these claims are not obvious in view of Ginsburg and Jordan and the Examiner is requested to withdraw the rejection of these claims based upon these references.

Dependent claims 48, 49, 51, 52, 53, 60, 61 and 63-65 depend from one of claims 47 and 59 and thus include all of the limitations of their parent claims. Accordingly, these dependent claims are not obvious in view of Ginsburg and Jordan, and the Examiner is requested to withdraw the rejections to these claims based upon these references.

Regarding the rejection of claims 47 and 59 as being obvious over Kashyap in view of Jordan, Kashyap describes a microwave apparatus for heating liquid in a closed plastic container, where the apparatus includes a cavity 5 that is energized by a microwave source to heat a bag 1

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disposed within the cavity (see Col. 2, line 61 to Col. 3, line 16 and Figures 1, 2 and 5 of Kashyap). A bag holder 8 including a shaft 9 are provided within the cavity 5 of the microwave apparatus of Kashyap, and a temperature detector 11 is mounted on the shaft 9 to be in contact with the bag 1. The temperature detector 11 of Kashyap is connected with a temperature control circuit 12 and a control panel 7 to switch off the microwave apparatus when the bag 1 reaches a predetermined temperature.

As is the case with the devices described in Jordan and Ginsburg, Kashyap requires the use of a heating mechanism (i.e., a microwave source) in combination with a temperature detector to control heating of a medical item placed within the device. Thus, Kashyap fails to disclose or suggest a medical device or a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device is configured such that thermal treatment of a medical item received within a receptacle of the medical device occurs only via heat transfer between the medical item and an external environment surrounding the medical device as recited in claims 47 and 59. Since Jordan also fails to disclose or suggest the combined features of each of claims 47 and 59, there is no combination of Kashyap and Jordan that describes or suggests every recited feature of each of claims 47 and 59. Accordingly, these claims are not obvious in view of Kashyap and Jordan and the Examiner is requested to withdraw the rejection of these claims based upon these references.

Dependent claims 48, 49, 52, 54, 55, 58, 60, 61, 64, 66 and 67 depend from one of claims 47 and 59 and thus include all of the limitations of their parent claims. Accordingly, these dependent claims are not obvious in view of Kashyap and Jordan, and the Examiner is requested to withdraw the rejections to these claims based upon these references.

New claims 69 and 70 depend from one of independent claims 47 and 59, and thus include all of the features of their parent claims and should be allowed over the cited art based upon the previous remarks. In addition, claims 69 and 70 recite the additional feature that said temperature sensor assembly is affixed to one of said first panel, said second panel and said base. None of the cited references relied upon by the Examiner to reject the claims discloses or suggests the feature of a temperature sensor assembly being affixed on a single wall, where the

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temperature sensor assembly directly measures a medical item temperature and visually indicates the measured medical item temperature. For example, each of Jordan and Shah describes a temperature sensor that is disposed on a separate wall or element than a visual temperature display. Accordingly, claims 69 and 70 should be allowed for their further recited features in addition to the remarks provided above for claims 47 and 59.

New independent claim 71 recites a medical device for visually indicating a temperature of a medical item placed therein comprising: a base and at least first and second panels attached to said base; a receptacle defined between said first and second panels for receiving said medical item within said receptacle, wherein said medical item has a particular temperature range for utilization; and a temperature sensor assembly to directly measure medical item temperature and visually indicate said measured medical item temperature, wherein said temperature sensor assembly is affixed to one of said first panel, said second panel and said base.

Similarly, new independent claim 72 recites a method of visually indicating a temperature of a medical item placed in a medical device, wherein said medical device includes a base and at least first and second panels attached to said base and a receptacle defined between said first and second panels, said method comprising the steps of: (a) receiving said medical item within said receptacle defined between said first and second panels of said device, wherein said medical item has a particular temperature range for utilization; and (b) directly measuring a medical item temperature and providing a visual indication of said measured medical item temperature via a temperature sensor assembly, wherein the temperature sensor assembly is affixed to one of the first panel, the second panel and the base.

As noted above for claims 69 and 70, none of the cited references relied upon by the Examiner to reject the claims discloses or suggests the feature of a temperature sensor assembly being affixed on a single wall, where the temperature sensor assembly directly measures a medical item temperature and visually indicates the measured medical item temperature. Thus, claims 71 and 72 are not anticipated or rendered obvious by any combination of the cited references, and allowance of these claims is respectfully solicited.

In view of the foregoing, the Examiner is respectfully requested to find the application to

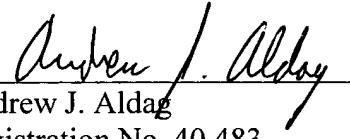
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be in condition for allowance with claims 47-72. However, if for any reason the Examiner feels that the application is not now in condition for allowance, the Examiner is respectfully requested to call the undersigned attorney to discuss any unresolved issues and to expedite the disposition of the application.

Applicant hereby petitions for any extension of time that may be required to maintain the pendency of this case, and any required fee for such extension is to be charged to Deposit Account No. 05-0460.

Respectfully submitted,

  
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Andrew J. Aldag  
Registration No. 40,483

EDELL, SHAPIRO & FINNAN, LLC  
1901 Research Boulevard, Suite 400  
Rockville, Maryland 20850-3164  
(301) 424-3640  
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